

## **Breast Cancer Surveillance Consortium Collaborative Research Agreement**

1. Project Title and Abstract Number:
2. Project Leader:
3. SCC Contact:
4. Co-investigators:
5. BCSC Abstract Approval Date:
6. Purpose of data request (check all that apply):
  - ☐ data analysis for manuscript
  - ☐ preliminary data for grant proposal
  - ☐ inputs for simulation model
  - ☐ development of statistical methods
  - ☐ other \_\_\_\_\_ (describe)

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### **Agreement**

This Breast Cancer Surveillance Consortium (BCSC) Collaborative Research Agreement (“Agreement”) is made and entered into as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_ by and between the BCSC and \_\_\_\_\_ (“Data Recipient”). This Agreement sets forth the terms and conditions pursuant to which the BCSC will disclose the Data Set or Data Tables to the Data Recipient.

Except as otherwise specified herein, Data Recipient may make all uses and disclosures of the Data Set/Tables to conduct the approved research project named above and described in the attached project proposal, and for no other purpose.

Only the project investigator, co-investigators, or designated individual(s) are permitted to use or receive the Data Set/Tables for approved purposes. These individuals are responsible for using this information subject to the terms and conditions of this Agreement.

### **Obligations of Data Recipient**

1. Data Recipient agrees to not use or disclose the Data Set/Tables for any other purpose other than as permitted by this Agreement. If the recipient would like to use the data for another purpose other than what is stated in their data request form, she/he is required to submit a new data request form to the BCSC to use the data for purposes other than those stated in this agreement.

2. Data Recipient agrees to use appropriate Security to prevent the use or disclosure of the Data Set/Tables other than as provided for by this Agreement.
3. Data Recipient will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it, as described in the proposal. Data Recipient agrees to report to the SCC contact any use or disclosure of the Data Set/Tables not permitted by this Agreement of which he/she becomes aware.
4. Data Recipient agrees to obtain IRB approval at their institution for any requests of individual-level data (i.e., not aggregate data). The SCC will not release individual-level data until proof of IRB approval or exemption is obtained.
5. Data Recipient will not permit others to use the data except for collaborations within their institution involved with the research as described in the proposal. Collaborators outside of the data recipient's institution must sign a Collaborative Research Agreement if they are custodians of the data.
6. If Data Recipient moves to another institution, he/she will notify the SCC in writing within 30 days regarding disposition of these BCSC data. If Data Recipient takes these BCSC data, then he/she must provide the SCC with updated contact information and a copy of the new IRB approval for the new institution. If the data remain at the initial organization, then the Data Recipient must designate who is responsible for the files and insure that he/she signs a copy of the Collaborative Research Agreement.
7. Data Recipient will not attempt to link nor permit others to link the BCSC data with individually identified records in another database.
8. No one having access to the BCSC data will attempt to learn the identity of any persons, radiologists, facilities, or BCSC sites. In the event that Data Recipient or collaborator is able to deduce the identity of a specific patient, radiologist, facility, or BCSC site he/she will agree to not attempt to contact these individuals or institutions.
9. No findings or information derived from the BCSC data may be released if such findings contain any combination of data elements that might allow the deduction of a patient's, radiologist's, facility's, or BCSC site's identity. In tables, cell sizes less than 5 must be suppressed. The BCSC proposal review committee will be the sole judge as to whether any finding derived from the BCSC data would, with reasonable effort, permit one to identify an individual, radiologist, facility, or BCSC site, or to deduce the identify of an individual or provider to a reasonable degree of certainty.
10. Data Recipient agrees to provide the BCSC or Designee(s) with a copy of all manuscripts using BCSC data prior to submission for publication or formal presentation. Data Recipient also agrees to not submit such findings to any third party until receiving approval to do so. The BCSC or Designee(s) agree to make a determination about approval and to notify the user within 4 weeks after receipt of any findings.

Review of findings is for the main purpose of assuring that data confidentiality is maintained and that individual patients, radiologists, facilities, or BCSC sites cannot be identified. The BCSC or Designee may withhold approval for publication if it determines that the format in which data are presented may result in identification of individual patients, radiologists, facilities, or BCSC sites.

Data Recipient agrees that in the event the BCSC determines or has reasonable belief that he/she has violated any terms of this agreement, the BCSC may request that he/she return the data and all derivative files to the SCC. Additionally, as a result of the BCSC's determination or reasonable belief that a violation of this agreement has taken place, the BCSC may refuse to release further BCSC data.

11. Data Recipient agrees to complete a brief progress report biannually.
12. Any publications and presentations will properly acknowledge the contributions of the BCSC as described in the Data Request Process Guide.
13. The SCC will serve as the repository of the final analytic datasets. The Data Recipient is asked to destroy BCSC datasets six months after publication of their results and/or completion of grant funding period.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first written above.

### **Breast Cancer Surveillance Consortium**

By: \_\_\_\_\_  
(signature of SCC Principal Investigator or Designee)

\_\_\_\_\_  
(print name)

Title: \_\_\_\_\_

### **Signature of Principal Investigator:**

The undersigned individual represents and warrants that he/she has authority to execute this Agreement on behalf of the Data Recipient (in the case of students and fellows, the department chair or advisor from the student's academic institution must sign the data request).

Your signature indicates that you agree to comply with the above stated provisions.

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Institution/Organization: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP code: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-Mail: \_\_\_\_\_

**Signature of the Custodian of the Data** (complete this if the data will be stored by someone other than the Principal Investigator)

Your signature indicates that you agree to comply with the above stated provisions.

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Institution/Organization: \_\_\_\_\_  
Street Address: \_\_\_\_\_  
City/State/ZIP code: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-Mail: \_\_\_\_\_